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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,137	11/18/2003	Ling Yuk Cheung	KONG-29	7246
1473	7590	07/28/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,137

Applicant(s)

CHEUNG, LING YUK

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0305 and 0405.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on 03/14/2005 and 04/11/2005 have been entered.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 03/14/2005 and 04/11/2005 were filed after the mailing date of the Notice of Allowance and Fee Dues on 12/14/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under USC 112, first paragraph, because the claimed invention is not deemed enabled without complete evidence either that the claimed

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biological materials are known and readily available to the public or complete evidence of the deposit of the biological material.

It is apparent that the microorganisms are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. ' 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. ' 1.802.

The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganisms are readily available to the public. The specification must contain the date that the microorganisms were deposited, the name of the microorganisms and the address of where the microorganisms were deposited.

If the deposits have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in position to make such assurances, or a statement by an attorney or record over his or her signature, and registration number, stating that the specific strains have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 C.F.R. ' 1.808.

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If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth 37 C.F.R. ' 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent , whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. ' 1.807; and

(e) the deposit will be replaced should it become necessary due to inviablilty, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. ' 1.809(d) should be added to the specification. See 37 C.F.R. ' 1.803-1.809 for additional explanation of these requirements. .

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a yeast composition and method for its preparation and administration comprising EMF exposure of *Saccharomyces cerevisia* for the treatment of epilepsy, the specification does not enable any person in the art in preparing a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 4 for the treatment of epilepsy.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a yeast composition and method for its preparation and administration comprising EMF exposure of yeast species selected from the group consisting of claim 4 for the treatment of epilepsy. Applicant has reasonably demonstrated on page 20 table 2 and page 21 table 3 of the specification, a yeast composition and method for its preparation and administration comprising EMF exposure of *Saccharomyces cerevisia* for the treatment of epilepsy. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a yeast composition and method for its preparation and

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administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 4 for the treatment of epilepsy.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 4 for the treatment of epilepsy. For example, Artman et al. teach (US 6589994 see, e.g. column 6 lines 24-28) that epilepsy is a common disorder with many causes, and can be difficult to treat. Thus, the art is silent regarding the efficacy of applicant's yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 4 for the treatment of epilepsy. Therefore, applicant's claimed yeast composition and/or methods is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on page 20 table 2 and page 21 table 3 of the specification, a yeast composition and method for its preparation and administration comprising EMF exposure of *Saccharomyces cerevisia* for the treatment of epilepsy. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 4 for the treatment of epilepsy.

Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CHRISTOPHER R. TATE
PRIMARY EXAMINER